Berlex Laboratories

Protocol 305602: A Multinational Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Ad5FGF-4 in Patients with Stable Angina

TECHNICAL ABSTRACT

Date: **Dec 19, 2001**
Amended: April 10, 2002

Amended: November 20, 2002

Study phase:	2B/3
Investigational Product, dosage, and route of administration:	Ad5FGF-4, E1 deleted human adenovirus serotype 5 with an hFGF-4 insert driven by a CMV promoter. Placebo will consist of an identical-appearing vehicle. The two doses studied will be 1.0 X 10^9 viral particles (2.87x10^8 total particles) and 1.0 X 10^{10} viral particles (2.87X10^9 total particles). Product will be administered via intra-coronary injection as a single dose.
Indication	Stable angina.
Primary Study objectives	To evaluate the efficacy and safety of Ad5FGF-4.
Patient population	Patients with stable angina, Canadian Cardiovascular Society (CCS) Classes 2 to 4 who are symptomatic despite medication and who are not optimal candidates for revascularization (coronary artery bypass graft [CABG] or percutaneous transluminal coronary angioplasty [PTCA]).
Study design	Randomized, parallel group, placebo controlled, double-blind.
Interim analyses	After approximately 27%, and 50% of patients have completed 12 weeks of follow-up by independent Data Safety Monitoring Board.
Concurrent control	Matching placebo.
Duration of observation	Up to 15 years, with clinic visits every year for 5 years.
Methodology	Baseline exercise treadmill testing. Intra-coronary administration of study product to patients with demonstrated angina limiting exercise capacity. Repeat exercise testing at week 4, week 12 and month 6.

Number of study centers	Up to 100
Total number of patients	450 patients receiving study product (Up to 350 of these to be included in the UK)
Known potential adverse events	Adenoviral and growth factor related.
Plan for data analysis	Intention-to-treat analysis, last observation carried forward.
Planned start and end of recruitment	Start of recruitment Q1 2002 End of recruitment Q3 2004
Manufacturer(s) of the investigational/reference product(s)	Berlex Biosciences, Richmond, California.